

unit at your institution) (refused to continue existing ROTC programs at your institution) (prevented students from participation at a Senior ROTC program at another institution) by a policy or practice of the College. Current law¹ prohibits funds by grant or contract (including a grant of funds to be available for student aid) from appropriations of the Departments of Defense, Labor, Health and Human Services, Education, and Related Agencies to schools that have a policy or practice prohibiting or preventing the Secretary of Defense from maintaining, establishing, or efficiently operating a Senior ROTC unit. Those statutes also bar agency funds for schools that prohibit or prevent a student from enrolling in an ROTC unit at another institution of higher education. Implementing regulations are codified at 32 Code of Federal Regulations, part 216.

This letter provides you an opportunity to clarify your institution's policy regarding ROTC access on the campus of ABC College. In that regard, I request, within the next 30 days, a written statement of the institution with respect to (define the problem area(s)).

Based on this information, Department of Defense officials will make a determination as to your institution's eligibility to receive funds by grant or contract. The decision may affect eligibility for funding from appropriations of the Departments of Defense, Labor, Health and Human Services, Education, and Related Agencies. Should it be determined that ABC College is in violation of the aforementioned statutes, such funding would be stopped, and the school would be ineligible to receive such funds in the future.

I regret that this action may have to be taken. Successful officer procurement requires that the Department of Defense maintain a strong ROTC program. I hope it will be possible to (define the correction to the aforementioned problem area(s)). I am available to answer any questions.

PART 218—GUIDANCE FOR THE DETERMINATION AND REPORTING OF NUCLEAR RADIATION DOSE FOR DoD PARTICIPANTS IN THE ATMOSPHERIC NUCLEAR TEST PROGRAM (1945-1962)

Sec.

218.1 Policies.

218.2 General procedures.

218.3 Dose reconstruction methodology.

218.4 Dose estimate reporting standards.

AUTHORITY: Pub. L. 98-542, 98 Stat. 2725 (38 U.S.C. 354 Note.)

SOURCE: 50 FR 42521, Oct. 21, 1985, unless otherwise noted.

§ 218.1 Policies.

(a) Upon request by the Veterans Administration in connection with a claim for compensation, or by a veteran or his or her representative, available information shall be provided by the applicable Military Service which shall include all material aspects of the radiation environment to which the veteran was exposed and shall include inhaled, ingested and neutron doses. In determining the veteran's dose, initial neutron, initial gamma, residual gamma, and internal (inhaled and ingested) alpha, beta, and gamma shall be considered. However, doses will be reported as gamma dose, neutron dose, and internal dose. The minimum standards for reporting dose estimates are set forth in § 218.4.

(b) The basic means by which to measure dose from exposure to ionizing radiation is the film badge. Of the estimated 220,000 Department of Defense participants in atmospheric nuclear weapons tests, about 145,000 have film badge dose data available. The information contained in the records has been reproduced in a standard format and is being provided to each military service, which can use the film badge dose data to obtain a radiation dose for a particular individual from that service. This is done upon request from the individual, the individual's representative, the Veterans Administration, or others as authorized by the Privacy Act. Upon request, the participant or his or her authorized representative will be informed of the specific methodologies and assumptions employed in estimating his or her dose. The participant can use this information to obtain independent options regarding exposure.

(c) From 1945 through 1954, the DoD and Atomic Energy Commission (AEC) policy was to issue badges only to a portion of the personnel in a homogeneous unit such as a platoon of a battalion combat team, Naval ship or aircraft crew. Either one person was badged in a group performing the same function, or only personnel expected to be exposed to radiation were badged. After 1954, the policy was to badge all

¹ 10 U.S.C. 983 and 110 Stat. 3009.

personnel. But, some badges were unreadable and some records were lost or destroyed, as in the fire at the Federal Records Center in St. Louis. For these reasons the Nuclear Test Personnel Review (NTPR) Program has focused on determining the radiation dose for those personnel (about 75,000) who were not issued film badges or for whom film badge records are not available.

(d) In order to determine the radiation dose to individuals for whom film badge data are not available, alternative approaches are used as circumstances warrant. All approaches require investigation of individual or group activities and their relationship to the radiological environment. First, if it is apparent that personnel were not present in the radiological environment and had no other potential for exposure, then their dose is zero. Second, if some members of a group had film badge readings and others did not—and if all members had a common relationship with the radiological environment—then doses for unbadged personnel can be calculated. Third, where sufficient badge readings or a common relationship to the radiological environment does not exist, dose reconstruction is performed. This involves correlating a unit's or individual's detailed activities with the quantitatively determined radiological environment. The three approaches are described as follows:

(1) Activities of an individual or his unit are researched for the period of participation in an atmospheric nuclear test. Unit locations and movements are related to areas of radiation. If personnel were far distant from the nuclear detonation(s), did not experience fallout or enter a fallout area, and did not come in contact with radioactive samples or contaminated objects, they were judged to have received no dose.

(2) Film badge data from badged personnel may be used to estimate individual doses for unbadged personnel. First, a group of participants must be identified that have certain common characteristics and a similar potential for exposure to radiation. Such characteristics are: Individuals must be doing the same kind of work, referred to as

activity, and all members of the group must have a common relationship to the radiological environment in terms of time, location or other factors. Identification of these groups is based upon research of historical records, technical reports or correspondence. A military unit may consist of several groups or several units may comprise a single group. Using proven statistical methods, the badge data for each group is examined to determine if it adequately reflects the entire group, is valid for use in statistical calculations, or if the badge data indicate the group should be sub-divided into smaller groups. For a group that meets the tests described above, the mean dose, variance and confidence limits are determined. An estimated dose equal to 95% probability that the actual exposure did not exceed the estimate is assigned to unbadged personnel. This procedure is statistically sound and will insure that unbadged personnel are assigned doses much higher than the average/mean for the group.

(3) Dose reconstruction is performed if film badge data are unavailable for all or part of the period or radiation exposure, if film badge data are partially available but cannot be used statistically for calculations, special activities are indicated for specific individuals, or if other types of radiation exposures are indicated. In dose reconstruction, the conditions of exposure are reconstructed analytically to arrive at a radiation dose. Such reconstruction is not a new concept; it is standard scientific practice used by health physicists when the circumstances of a radiation exposure require investigation. The underlying method is in each case the same. The radiation environment is characterized in time and space, as are the activities and geometrical position of the individual. Thus, the rate at which radiation is accrued is determined throughout the time of exposure, from which the total dose is integrated. An uncertainty analysis of the reconstruction provides a calculated mean dose with confidence limits. The specific method used in a dose reconstruction depends on what type of data are available to provide the required characterizations as well as the nature of the radiation

§218.2

environment. The radiation environment is not limited to the gamma radiation that would have been measured by a film badge, but also includes neutron radiation for personnel sufficiently close to a nuclear detonation, as well as beta and alpha radiation (internally) for personnel whose activities indicate the possibility of inhalation or ingestion of radioactive particles.

§218.2 General procedures.

The following procedures govern the approach taken in dose determination:

(a) Use individual film badge data where available and complete, for determining the external gamma dose.

(b) Identify group activities and locations for period(s) of possible exposure.

(c) Qualitatively assess the radiation environment in order to delineate contaminated areas. If no activities occurred in these areas, and if no other potential for exposure exists, a no dose received estimate is made.

(d) If partial film badge data are available, define group(s) of personnel with common activities and relationships to radiation environment.

(e) Using standard statistical methods, verify from the distribution of film badge readings whether the badged sample adequately represents the intended group.

(f) Calculate the mean external gamma dose, with variance and confidence limits, for each unbadged population. Assign a dose equal to 95% probability that actual exposure did not exceed the assigned dose.

(g) If badge data is not available for a statistical calculation, conduct a dose reconstruction.

(h) For dose reconstruction, define radiation environment through use of all available scientific data, e.g., measurements of radiation intensity, decay, radioisotopic composition.

(i) Quantitatively relate activities shielding, position, and other factors to radiation environment as a function of time. Integrate dose throughout period of exposure.

(j) Where possible, calculate mean dose with confidence limits; otherwise calculate best estimate dose or, if data are too sparse, upper limit dose.

(k) Compare calculations with available film badge records to verify the

32 CFR Ch. I (7–1–04 Edition)

calculated doses. Whether or not film badge data is available, calculate initial and internal doses where identified as a meaningful contribution to the total dose.

§218.3 Dose reconstruction methodology.

(a) *Concept.* The specific methodology consists of the characterization of the radiation environments to which participants through all relevant activities, were exposed. The environments, both initial and residual radiation are corrected with the activities of participants to determine accrued doses due to initial radiation, residual radiation and/or inhaled/ingested radioactive material, as warranted by the radiation environment and the specific personnel activities. Due to the range of activities, times, geometries, shielding, and weapon characteristics, as well as the normal spread in the available data pertaining to the radiation environment, an uncertainty analysis is performed. This analysis quantifies the uncertainties due to time/space variations, group size, and available data. Due to the large amounts of data, an automated (computer-assisted) procedure is often used to facilitate the data-handling and the dose integration, and to investigate the sensitivity to variations in the parameters used. The results of the gamma data calculations are then compared with film badge data as they apply to the specific period of the film badges and to the comparable activities of the exposed personnel, in order to validate the procedure and to identify personnel activities that could have led to atypical doses. Radiation dose from neutrons and dose commitments due to inhaled or ingested radioactive material are not detected by film badges. Where required, these values are calculated and recorded separately.

(b) *Characterization of the radiological environment.* (1) This step describes and defines the radiological conditions as a function of time for all locations of concern, that is, where personnel were positioned or where personnel activities took place. The radiation environment is divided into two standard categories—initial radiation and residual radiation.

(2) The initial radiation environment results from several types of gamma and neutron emissions. Prompt neutron and gamma radiation are emitted at the time of detonation, while delayed neutrons and fission-product gamma, from the decay of radioactive products in the fireball, continue to be emitted as the fireball rises. In contrast to these essentially point sources of radiation, there is gamma radiation from neutron interactions with air and soil, generated within a fraction of a second. Because of the complexity of these radiation sources and their varied interaction properties with air and soil, it is necessary to obtain solutions of the Boltzmann radiation transport equation. The radiation environment thus derived includes the effects of shot-specific parameters such as weapon type and yield, neutron and gamma output, source and target geometry, and atmospheric conditions. The calculated neutron and gamma radiation environments are checked for consistency with existing measured data as available. In those few cases displaying significant discrepancies that cannot be resolved, an environment based on extrapolation of the data is used if it leads to a larger calculated dose.

(3) In determining the residual radiation environment, all possible sources are considered including radioactive clouds, radiation that may have been encountered from other tests, and radioactive debris that may have been deposited in water during oceanic tests. The residual radiation environment is divided into two general components—neutron-activated material that subsequently emits, over a period of time, beta and gamma radiation; and radioactive debris from the fission reaction or from unfissioned materials that emit alpha, beta, and gamma radiation. Because residual radiation decays, the characterization of the residual environment is defined by the radiation intensity as a function of type and time. Radiological survey data are used to determine specific intensities at times of personnel exposure. Interpolation and extrapolation are based on known decay characteristics of the individual materials that comprise the residual contamination. In those rare cases where insufficient radiation data

exist to adequately define the residual environment, source data are obtained from the appropriate weapon design laboratory and applied in standard radiation transport codes to determine the initial radiation at specific distances from the burst. This radiation, together with material composition and characteristics, leads to description of the neutron-activated field for each location and time of interest. In all cases observed data, as obtained at the time of the operation, are used to calibrate the calculations.

(c) *Activities of participants.* This step uses all official records, augmented by personnel interviews where gaps exist, to depict a scenario of activities for each individual or definable group. When a dose reconstruction is performed for a specific individual, information available from the individual is accepted unless demonstrably inaccurate. For military units, whose operations were closely controlled and further constrained by radiological safety monitors, the scenario is usually well defined. The same is true for observers, who were restricted to specific locations both during and after the nuclear burst. Ships' locations and activities are usually known with a high degree of precision from deck logs. Aircraft tracks and altitudes are also usually well defined. Personnel engaged in scientific experiments often kept logs of their activities; moreover, the locations of their experiments are usually a matter of record. Where the records are insufficiently complete for the degree of precision required to determine radiation exposure, participants' comments are used and reasonable judgements are made to further the analysis. Possible variations in the activities, as well as possible individual deviations from group activities, with respect to both time and location, are considered in the uncertainty analysis of the radiation dose calculations.

(d) *Calculation of dose.* (1) The initial radiation doses to close-in personnel (who were normally positioned in trenches at the time of detonation) are calculated from the above-ground environment by simulating the radiation transport into the trenches. Various calculational approaches, standard in health physics, are employed to relate

in-trench to above-trench doses for each source of radiation. Detailed modeling of the human body, in appropriate postures in the trench, is performed to calculate the gamma dose that would have been recorded on a film badge and the maximum neutron dose. The neutron, neutron-generated gamma, and prompt gamma doses are accrued during such a short time interval that the posture in a trench could not be altered significantly during this exposure. The fission-product gamma dose, however, is delivered over a period of many seconds. Therefore, the possibility of individual reorientation (e.g., standing up) in the trench is considered.

(2) The calculation of the dose from residual radiation follows from the characterized radiation environment and personnel activities. Because radiation intensities are calculated for a field (i.e., in two spatial dimensions) and in time, the radiation intensity is determinable for each increment of personnel activity regardless of direction or at what time. The dose from exposure to a radiation field is obtained by summing the contribution (product of intensity and time) to dose at each step. The dose calculated from the radiation field does not reflect the shielding of the film badge afforded by the human body. This shielding has been determined for pertinent body positions by the solution of radiation transport equations as applied to a radiation field. Conversion factors are used to arrive at a calculated film badge dose, which not only facilitates comparison with film badge data, but serves as a substitute for an unavailable film badge reading.

(3) The calculation of the dose from inhaled or ingested radioactivity primarily involves the determination of what radionuclides entered the body in what quantity. Published conversion factors are then applied to these data to arrive at the radiation dose and future dose commitments to internal organs. Inhalation or ingestion of radioactive material is calculated from the radioactive environment and the processes of making these materials inhalable or ingestible. Activities and processes that cause material to become airborne (such as wind, decon-

tamination or traffic) are used with empirical data on particle lofting to determine airborne concentrations under specific circumstances. Volumetric breathing rates and durations of exposure are used to calculate the total material intake. Data on time-dependent weapon debris isotopic composition and the above-mentioned conversion factors are used to calculate the dose commitment to the body and to specific body organs.

(e) *Uncertainty analysis.* Because of the uncertainties associated with the radiological data or calculations used in the absence of data, as well as the uncertainties with respect to personnel activities, confidence limits are determined where possible for group dose calculations. The uncertainty analysis quantifies the errors in available data or in the model used in the absence of data. Confidence limits are based on the uncertainty of all relevant input parameters, and thus vary with the quality of the input data. They also consider the possible range of doses due to the size of the exposure group being examined. Typical sources of error include orientation of the weapons, specific weapon yields, instrument error, fallout intensity data, time(s) at which data were obtained, fallout decay rate, route of personnel movements, and arrival/stay times for specific activities.

(f) *Comparison with film badge records.* (1) Calculations of gamma dose were compared with film badge records for two military units at Operation PLUMBBOB to initially validate this methodology. Where all parameters relating to radiation exposure were identified, direct comparison of gamma dose calculations with actual film badge readings was possible. Resultant correlations provided high confidence in the methodology.

(2) Film badge data may, in some cases, be unrepresentative of the total exposure of a given individual or group; nevertheless, they are extremely useful for direct comparison of incremental doses for specific periods, e.g., validating the calculations for the remaining, unbadged period of exposure. Moreover, a wide distribution of film badge data often leads to more definitive personnel grouping for dose calculations

and to further investigation of the reason(s) for such distribution. In all cases, personnel film badge data are not used in the dose calculations, but rather are used solely for comparison with and validation of the calculations. For dose reconstructions accomplished to date, comparison has been favorable and within the confidence limits of the calculations.

§ 218.4 Dose estimate reporting standards.

The following minimum standards for reporting dose estimates shall be uniformly applied by the Military Services when preparing information in response to an inquiry by the Veterans Administration, in connection with a claim for compensation, or by a veteran or his or her representative. The information shall include all material aspects of the radiation environment to which the veteran was exposed and shall include inhaled, ingested, and neutron doses, when applicable. In determining the veteran's dose, initial neutron, initial gamma, residual gamma, and internal (inhaled and ingested) alpha, beta, and gamma shall be considered. However, doses will be reported as gamma dose, neutron dose, and internal dose. To the extent to which the information is available, the responses will address the following questions:

(a) Can it be documented that the veteran was a test participant? If so, what tests did he attend and what were the specifics of these tests (date, time, yield (unless classified) type, location and other relevant details)?

(b) What unit was the man in? What were the mission and activities of the units at the test?

(c) To the extent to which the available records indicate, what were his duties at the test?

(d) Can you corroborate the specific information relevant to the potential exposure provided by the claimant to the Veterans Administration and forwarded to the Department of Defense? What is the impact of these specific activities on the claimant's reconstructed dose?

(e) Is there any recorded radiation exposure for the individual? Does this recorded exposure cover the full period

of test participation? What are the uncertainties associated with the recorded film badge dose?

(f) If recorded dosimetry data is unavailable or incomplete, what is the dose reconstruction for the most probable dose, with error limits, if available?

(g) Is there evidence of a neutron or internal exposure? What is the reconstruction?

Upon request, the participant or his or her authorized representative will be informed of the specific methodologies and assumptions employed in estimating his or her dose.

PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

219.101 To what does this policy apply?

219.102 Definitions.

219.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

219.104–219.106 [Reserved]

219.107 IRB membership.

219.108 IRB functions and operations.

219.109 IRB review of research.

219.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

219.111 Criteria for IRB approval of research.

219.112 Review by institution.

219.113 Suspension or termination of IRB approval of research.

219.114 Cooperative research.

219.115 IRB records.

219.116 General requirements for informed consent.

219.117 Documentation of informed consent.

219.118 Applications and proposals lacking definite plans for involvement of human subjects.

219.119 Research undertaken without the intention of involving human subjects.

219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

219.121 [Reserved]

219.122 Use of Federal funds.

219.123 Early termination of research support: Evaluation of applications and proposals.

219.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.